DEC - 7 2004

510(k) SUMMARY

Prepared:	November 13, 2004
Submitter:	Hach Company
Address:	23575 County Road 106 Elkhart, IN 46514 U.S.A. (219) 262-2060
Contact:	David A. Morris, Ph.D. Director of Technology
Device Trade/ Proprietary Name:	SteriChek® Blood Leak Reagent Strips, 510(k) No. K042322
Device Common Name:	Blood Leak Reagent Strips
Classification Name:	21 CFR 876.5820 Hemodialysis system and accessories, Class II
Product Code:	78-FJD
Predicate Device:	Serim™ Blood Leak Test Strips, 510(k) No. K012115 and K990206
Device Description:	The device is made up of a 0.20 inch square yellow reagent pad that has been chemically treated to detect the presence of blood in the dialysate solution used in Hemodialysis. The pad is affixed to one end of a 3.25 inch by 0.20 inch white opaque polystyrene strip. To use the reagent strip, the reagent pad is immersed in the sample, removed immediately and allowed to react for 60 seconds. The reagent pad is then compared with the color blocks on the bottle label. The Negative color block is yellow with small blue-green speckles. If a reagent pad has a similar yellow color 60 seconds after reaction with dialysate, then the dialysate does not contain significant blood. The Positive color block is green. A reagent pad with color equal to or darker than the Positive color block indicates the presence of significant blood leak. The speckles on the color blocks represent the reaction image that might be left by intact red blood cells that might land on the reagent pad.
Intended Use:	SteriChek Blood Leak Reagent Strips provide a quick convenient means of testing for occult blood in dialysate.

The Association for the Advancement of Medical Instrumentation (AAMI) (1) recommends that all Hemodialysis systems shall have a method of detecting blood in the dialysate. In the alarm condition the detector shall initiate audible and visual alarms. The high alarm limit shall be not more than 0.35 mL/minute for a fixed alarm limit at a hematocrit of 25% (0.25). The leak rate of 0.35 mL/minute calculates to a level of 5.5 mg/dL of hemoglobin in the dialysate, assuming a hematocrit of 25% and a dialysate flow of 0.5 L/minute). For many years, Hemodialysis technicians have used reagent strips to assist in differentiating an actual blood leak from a false alarm to avoid unnecessary interruption of the Hemodialysis procedure. A confirmed blood leak requires termination of the dialysis session and restarting with a new dialyzer. Interrupting a dialysis session can be very stressful to the patient.

SteriChek Blood Leak Reagent Strips detect very low levels of blood in dialysate. The reagent strips give positive readings at 1.5 mg/dL of hemoglobin. The reagent strips are more sensitive than the AAMI recommended setting of 5.5 mg/dL for blood leak monitors. This increased sensitivity of the reagent strips provides a safety margin.

Technological Characteristics: Reagent strip method to test for occult blood by color change resulting from a reaction between an indicator and an oxidant when hemoglobin from red blood cells is present.

Assessment of Performance: The performance characteristics of SteriChek® Blood Leak Reagent Strips and Serim™ Blood Leak Test Strips were analyzed with suspensions of whole blood in dialysate and solutions of human hemoglobin in dialysate. The hemoglobin was measured with the Drabkin spectrophotometric method. The sensitivity of the reagent strip methods was equivalent.

The Drabkin method is the standard used in most laboratories. In this method, hemoglobin or oxyhemoglobin is converted to a stable pigment called cyanmethemoglobin by adding the blood sample to alkaline "Drabkin's solution". Drabkin's solution contains potassium ferricyanide, potassium cyanide, sodium bicarbonate and a surfactant. The absorbance of the stable pigment is measured at 540 nm with a spectrophotometer. The absorbance value is a measure of the hemoglobin present in the sample.

Conclusion: The SteriChek® Blood Leak Reagent Strips have the same intended use as the predicate device. The SteriChek® Blood Leak Reagent Strips have no technological characteristics that raise new types of safety or effectiveness questions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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David A. Morris, Ph.D.
Director of Technology
Hach® Company
23575 County Road 106
ELKHART IN 46514

Re: K042322
Trade/Device Name: SteriChek® Blood Leak Reagent Strips
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: 78 FJD
Dated: November 13, 2004
Received: November 15, 2004

Dear Dr. Morris:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known) K042322

Device Name: SteriChek® Blood Leak Reagent Strips.

Indications for Use:

SteriChek® Blood Leak Reagent Strips provide a quick convenient means of checking the presence of Blood in dialysate to assist in confirming an alarm by the blood leak monitor of the Hemodialysis machine.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED).

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042322